REMARKS

Claims 1-21 are currently pending.

Amendments to the Claims

Claim 1 is amended to clarify that the at least one fluid entry port is formed on an internal portion of the coil-shaped region *with an external portion of the coil-shaped region being port-free.* Support for this amendment can be found throughout the specification and in the drawings, for example, at page 8, lines 19-25 and in Figure 4. Claim 3 is amended into independent format to include all of the limitations of original claim 1. Claim 14 is reworded to clarify the claimed subject matter. No new matter is added.

Applicants also add new claims 19-21.

New independent claim 19 recites an implantable fluid management device having a catheter with an inner lumen extending between proximal and distal ends, and a coil-shaped region formed on the distal end of the catheter and having successive turns that are spaced apart from one another by a distance that is adapted to prevent tissue from growing into the coil-shaped region. Claim 19 further recites at least one fluid entry port in communication with the inner lumen and formed internal to the coil-shaped region such that the at least one fluid entry port is sheltered by the coil-shaped region. New claim 20 depends from claim 19 and specifies that the distance between each successive turn of the coil-shaped region is in the range of about 0 to 2 mm. Support for new claims 19 and 20 can be found throughout the specification and in the drawings, for example, at page 7, line 25 to page 8, line 2, and at page 8, lines 19-25. No new matter is added.

New independent claim 21 recites an implantable fluid management kit having a catheter with an inner lumen extending between proximal and distal ends, and a coil-shaped region formed on the distal end and including at least one fluid-entry port formed on an internal portion thereof with an external portion of the coil-shaped region being port-free. Claim 21 further recites a stylet that is adapted to be removably disposed within the inner lumen of the catheter and that has a substantially elongate configuration such that the stylet is effective to straighten the coil-shaped region when the stylet is disposed within the catheter. Support for this amendment can also be found throughout the

specification and in the drawings, for example, at page 4, lines 3-8, page 8, lines 19-25, page 9, line 23 to page 10, line 10, and in Figure 4. No new matter is added.

Rejection Pursuant to 35 U.S.C. §102

Claims 1, 8-10, and 14-18 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,141,502 of Macaluso, Jr. (Macaluso). The Examiner, referring to Figures 7 and 9, argues that Macaluso discloses a catheter having a distal tube body with a coil-shaped region formed on a distal end thereof and having one or more fluid entry ports formed therein, as recited in independent claim 1. Applicants respectfully disagree.

Independent claim 1 recites an implantable fluid management device that includes a catheter having a coil-shaped region formed in the distal portion, and at least one fluid entry port formed in the internal portion of the coil-shaped region with an external portion of the coil-shaped region being port-free. Macaluso does not teach or even suggest such a configuration. As shown in Figure 7, Macaluso discloses a ureteral stent having a double helix portion that is configured to be positioned in a patient's renal pelvis. While the helix portion includes pores 20 formed therein, the pores are not formed *in the internal portion of the coil-shaped region with an external portion of the coil-shaped region being port-free*, as required by independent claim 1. Rather, the pores are formed at various locations on the catheter, including *external* to the helix portion. Accordingly, Macaluso fails to teach or even suggest the claimed invention, and therefore claim 1 represents allowable subject matter. Applicants have advantageously provided a catheter having only internal ports on the coil region to prevent tissue and debris from clogging the ports.

Applicants also note that new independent claim 21 is allowable for the same reason as independent claim 1.

New claim 19 also distinguishes over Macaluso. In particular, claim 19 requires a coil-shaped region having successive turns that are spaced apart from one another by a distance that is adapted to prevent tissue from growing into the coil-shaped region. Macaluso does not teach or even suggest such a configuration. As shown in Figure 7, Macaluso discloses a helix that is loosely wound to fit within the renal pelvis, and thus that has successive turns that are spaced apart from one another by a significant distance. This distance is clearly large enough to allow tissue to grow into

the helix, and any modification of the distance between the turns on the Macaluso catheter would likely render the device inoperative for its intended use as the helix would no longer fit within the renal pelvis.

In sum, independent claims 1, 19, and 21 distinguish over Macaluso and therefore represent allowable subject matter. Claims 2, 4-18, and 20 are allowable at least because they depend from an allowable base claim.

Rejection Pursuant to 35 U.S.C. §103

Claims 2-7 and 11-13 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Macaluso in view of U.S. Patent No. 6,595,966 of Davey et al. (Davey). The Examiner admits that Macaluso fails to teach or even suggest the shaped inlet ports, the increasing diameter, and the size limitations recited in claims 2-7 and 11-13, thus the Examiner relies on Davey to disclose such features arguing that it would have been obvious to modify Macaluso in view of Davey to increase fluid flow and to provide an appropriately-dimensioned catheter. Applicants respectfully disagree.

At the outset, claims 2, 4-7, and 11-13 depend from claim 1, which, for reasons indicated above, distinguishes over Macaluso. Claims 2, 4-7, and 11-13 are therefore allowable. Applicants further submit that these claims are allowable because it would not have been obvious to modify Macaluso in view of Davey. These references disclose distinct inventions that are used for distinct purposes. No person having ordinary skill in the art would rely on Davey, which is directed to a *dialysis catheter*, to modify the *ureteral stent* disclosed by Macaluso. Moreover, the goal of Macaluso was to provide a stent "that offers superior columnar and axial strength for smooth advancement during insertion into a patient's ureter . . . ." (Abstract.) Davey does not provide any solutions to further the goal of Macaluso, rather Davey provides a catheter that increases flow therethrough. The Examiner has failed to point to teachings *present within the art itself* that suggests the claimed subject matter, and thus the Examiner's act of picking and choosing features out of context from different references to construct a prima facie obviousness rejection boils down to an impermissible hindsight reconstruction of Applicants' invention.

Applicants further submit that independent claim 3 distinguishes over Macaluso and Davey, taken alone or combined. Claim 3 requires a coil-shaped region formed on the distal portion of the

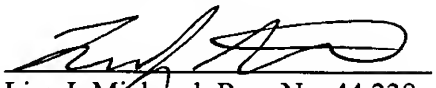
catheter that has an outer diameter that is substantially equal to an outer diameter of the proximal portion of the catheter. Such a configuration is particularly effective for use in treating hydrocephalus, where the diameter of the catheter must remain relatively small "to minimize the damage that may result during implantation of the fluid management device." (Pending Application, page 8, lines 17-18.) Macaluso does not teach or even suggest such a structure. As shown in Figure 7, the helix has an outer diameter that is significantly greater than an outer diameter of the catheter to allow the helix to fit "tightly within the renal pelvis 12, as shown in FIG. 3." (Col. 3, lines 50-51.) Since the helix is specifically shaped and sized to fit within the renal pelvis, it would not even have been obvious to modify Macaluso, in view of Davey or any other reference, to have a helix with an outer diameter that is substantially the same as the outer diameter of the catheter because the modification would render the device inoperative for its intended use. Accordingly, independent claim 3 distinguishes over Macaluso and Davey and therefore represents allowable subject matter.

Conclusion

In view of the amendments and remarks above, Applicants submit that claims 1-21 are in condition for allowance. In the event that the above amendments and remarks are not deemed to place this case in condition for allowance, an opportunity to interview with the Examiner is requested. Applicants encourage the Examiner to telephone the undersigned upon receipt of this response to discuss any issues that may remain.

Respectfully submitted,

Date: June 11, 2004



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